

Effects of implantation height on the performance of a redo transcatheter aortic valve replacement using a balloon-expandable valve



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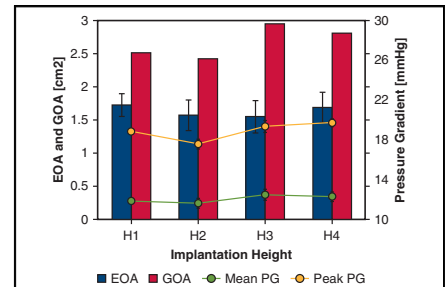
ABSTRACT

Objective: The use of the transcatheter aortic valve in low-risk patients might lead to a second intervention due to the deterioration of the first. Understanding the implantation height is key to an effective redo transcatheter aortic valve replacement treatment.

Methods: The effects of implantation height on the performance of a balloon-expandable valve within a self-expandable valve were assessed using hemodynamic testing and particle image velocimetry. The hemodynamic performances, leaflet kinematics, and turbulent shear stresses were measured and compared.

Results: When a second balloon-expandable valve was positioned at varying heights relative to the first self-expandable valve, the leaflet motion of the first valve transitioned from free opening and closing to overhanging, and eventually to being entirely pinned to the stent, forming a neo-skirt. When the leaflets of the self-expandable valve could move freely, a decrease in regurgitation fraction was observed, but with an increased pressure gradient across the valve. Flow visualization indicated that the overhanging leaflets disrupted the flow, generating a higher level of turbulence.

Conclusions: This study suggests that the overhanging leaflets should be avoided, whereas the other 2 scenarios should be carefully evaluated based on an individual patient's anatomy and the cause of failure of the first valve. (JTCVS Open 2024;19:61-7)



H1, H2, H3, H4: Different overlap length between Sapien3 and Evolut valves.

CENTRAL MESSAGE

The implantation height of the second TAVR affects the hemodynamics performance of redo TAVR. The optimal height is related to the patient's anatomy and the cause of failure of the first valve.

PERSPECTIVE

Choosing the optimal implantation height is key to an effective redo TAVR procedure. Using in vitro testing and PIV, we showed that the overhanging leaflets should be avoided. However, the selection between free-moving or pinned leaflets should be carefully evaluated based on the patient's anatomy and the cause of failure of the first valve.

As an alternative to invasive surgical aortic valve replacement, the minimally invasive transcatheter aortic valve (TAV) replacement (TAVR) has shown comparable

outcomes for low-risk patients, indicated by recently published preliminary results.¹⁻³ Although more data are needed to evaluate its long-term outcome, the Food and

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Abbreviations and Acronyms

EOA	= effective orifice area
GOA	= geometric orifice area
PG	= pressure gradient
PI	= pinwheeling index
PIV	= particle image velocimetry
RF	= regurgitant fraction
RSS	= Reynolds shear stress
TAV	= transcatheter aortic valve
TAVR	= transcatheter aortic valve replacement
ViV	= valve-in-valve

Drug Administration has approved TAVR to be used in all risk categories of patients. It is likely to result in more TAVR cases for younger patients, and their life expectancies could exceed the durability of the valve.⁴ To fix the failing TAVR, studies have suggested implanting a second TAV inside the prior TAV, known as redo TAVR or TAV-in-TAV.^{5,6} Although redo TAVR has been effective in treating failed TAVs due to regurgitation, stenosis, or a combination of the 2, the outcome depends on the patient's anatomy (such as coronary access due to risk of coronary obstruction) and the first (or index) TAV characteristics. Of all the parameters of concern, the selection of the second TAV and the implantation height are of the most importance, especially when the first 1 is a supra-annular self-expandable valve. If the implantation is too low, there is a leaflet overhanging from the first valve, whereas if the implantation is too high, the leaflets will be pinned to create a neo-skirt,^{7,8} which might cause problems in coronary access after the redo TAVR.

Past in vitro studies have focused on investigating the effects of the different second TAV implantation heights by assessing the hemodynamics and performance. Midha and colleagues⁹ examined the effects of implantation height of the TAVR on the hemodynamics after deploying TAVR in a failed surgical valve (Perimount; Edwards Lifesciences). Both balloon- and self-expandable valves were studied. Results showed an advantage in the supra-annular deployment of the balloon-expandable valve in terms of the outcome paravalvular leakage, transvalvular mean gradient, and leaflet kinematics. Akodad and colleagues⁸ looked at different implantation heights of a balloon-expandable valve in a supra-annular self-expandable valve. Hemodynamic evaluations have suggested that the implantation height does not significantly influence the competence of the valve, except for an increase in the regurgitant fraction for the large-sized valves. Also, they mention the possibility of obstructed coronary access after redo TAVR.⁸

In this article, the hemodynamics of a balloon-expandable valve (26-mm Sapien 3 Ultra; Edwards Lifesciences) deployed in a self-expandable valve (29-mm Evolut PRO+; Medtronic) with different implantation heights were studied

with the flow fields downstream of the valve evaluated by particle image velocimetry (PIV). Vorticity and Reynolds shear stress (RSS) fields were obtained and compared. This study offers insights into the optimal implantation height for a balloon-expandable valve within a supra-annular self-expandable valve.

METHODS

The first valve is a supra-annular 29-mm Evolut PRO+, and it was deployed based on the normal development height into a transparent idealized aortic root model without coronary arteries, which has a nominal aortic annulus size of 26 mm. The model has 3 independent sinus lobes and was based on an average of 15,000 patient-specific geometric data.¹⁰ The model was made by casting clear polydimethylsiloxane rubber using a lost core procedure.^{11,12} Details of the casting method and a drawing of the model are provided by Chen and Dasi.¹³

Subsequently, a 26-mm Sapien 3 Ultra was deployed in the first Evolut PRO+ at 4 different heights, as shown in Figure 1. The development was based on the rationale that the Evolut leaflets should be pinned to the stent at the highest deployment height and the leaflets should be free to move for the lowest deployment height. The development height is defined by the distance between the tip of the Sapien stem to the base of the Evolut and was measured by a caliper after deployment. The 4 heights were $H_1 = 24.5$ mm, $H_2 = 20.5$ mm, $H_3 = 16$ mm, and $H_4 = 12.5$ mm, all shown in Figure 1.

The valve-in-valve (ViV) model was later incorporated into a left heart simulator, which was designed and used extensively in our previous studies.¹⁴ Briefly, the simulator was driven by a bladder pump with a resistor and a capacitor element downstream to generate physiological hemodynamics. The flow and pressure were monitored by transducers and data were acquired by a LabVIEW (National Instrument) program at a sampling rate of 100 Hz. All the data are presented as mean \pm SD. The working fluid is a mixture of deionized water and glycerin (60:40 by volume, 1060 kg/m³), and the kinematic viscosity is about 3.5 cSt at the working temperature of 37 °C, matching that of the blood. The peak aortic flow rate was 25 ± 0.2 L/minute at a heart rate of 60 bpm. The systolic/diastolic pressure measured at the aortic side of the valve was $120/80 \pm 1$ mm Hg for all 4 sets of experiments, meeting the requirement outlined in the ISO 5840-3:2021 standard.¹⁵

To evaluate the hemodynamic parameters of the ViV, data from 60 consecutive cardiac cycles were recorded. The main parameters of interest are regurgitant fraction (RF) and the effective orifice area (EOA). RF is defined by Equation 1, which measures the percentage of the regurgitant volume during valve closure to the total stroke volume (forward flow volume) of the left ventricle. A smaller RF means better performance of the valve.

$$RF = \frac{\text{Regurgitant Volume [mL]}}{\text{Stroke Volume [mL]}} \times 100 \quad (1)$$

EOA is a parameter measuring the opening of the valve based on the hydrodynamic performance and is defined by Equation 2. Q represents the root mean square aortic valve flow and PG is the mean transvalvular aortic pressure gradient during a cardiac cycle.

$$EOA = \frac{Q \text{ [cm}^3\text{/s]}}{51.6 \sqrt{PG \text{ [mm Hg]}}} \quad (2)$$

To evaluate the kinematics of the leaflets, en face images were recorded by a monochromatic high-speed camera at a 1 kHz frame rate with a resolution of 1024^2 px². Geometric orifice area (GOA) and pinwheeling index (PI) were calculated based on the en face images. PI was calculated as Equation 3.⁹

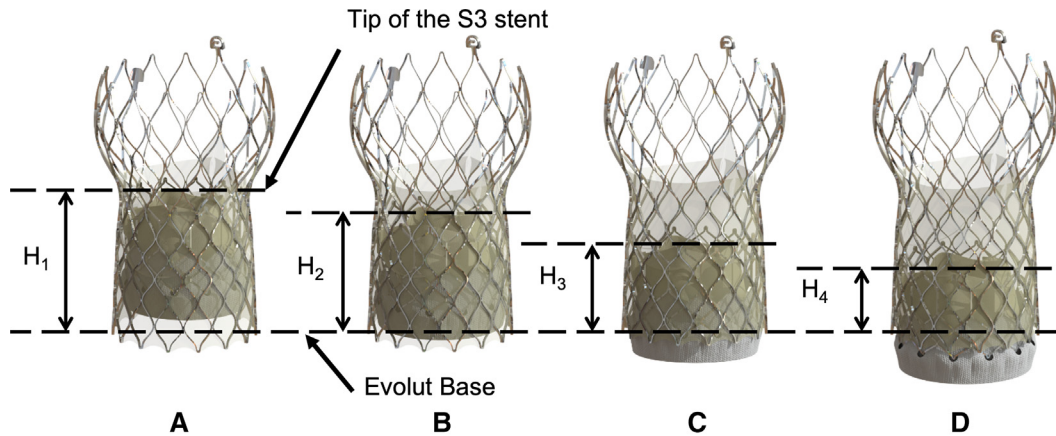


FIGURE 1. A-D, The deployment of a 26-mm Sapien 3 Ultra (Edwards Lifesciences) in a 29-mm Evolut PRO+ (Medtronic) at 4 different heights. The height is defined by the distance between the tip of the Sapien 3 stent to the base of the Evolut PRO+ valve. H₁ to H₄ represents the different overlapping heights of the two valves.

$$PI = \frac{L_{actual} - L_{ideal}}{L_{ideal}} \times 100 \quad (3)$$

where L_{actual} and L_{ideal} represent the deflected and unconstrained free edge of the leaflet, respectively.

Fluid flow patterns downstream of the TAV were assessed using phase-locked PIV with high spatial resolutions. Detailed PIV setup and data analysis can be found in Madukauwa-David and colleagues¹⁶ and Heitkemper and colleagues.¹⁷ Briefly, the flow field was seeded with 10 μm polyamide particles coated with rhodamine B. A thin laser sheet generated by expanding a beam from an Nd:YLF single cavity laser was used to illuminate the flow downstream of the valve. The laser sheet cuts through the center of the aortic root model and a high-speed camera with a resolution of 1024² px² was used to record the particle images, which were later processed in DaVis 10 (LaVision GmbH). The imaging system was synchronized with the bladder pump, and 200 consecutive image pairs were acquired at 3 different time points during a cardiac cycle: midacceleration, peak systole, and mid-deceleration. Velocity vector field and vorticity dynamics were evaluated

distal to the TAV for assessing the performance of the valve. The principal RSS (Equation 4), a quantity closely related to the hemolysis potential of the valve, was also calculated and presented.

$$RSS = \rho \sqrt{\left(\frac{u'u' - v'v'}{2}\right)^2 + (u'v')^2} \quad (4)$$

Where u' denotes the fluctuation term ($u' = u - U$, where u is the instantaneous velocity and U is the mean velocity.)

RESULTS

Hemodynamics Performance

The flow waveform measured at the aortic side of the valve and the RF for all cases are shown in Figure 2. The peak flow rate reaches 25 ± 0.2 L/minute for all cases, and the systole duration is about 35%. The closing volume

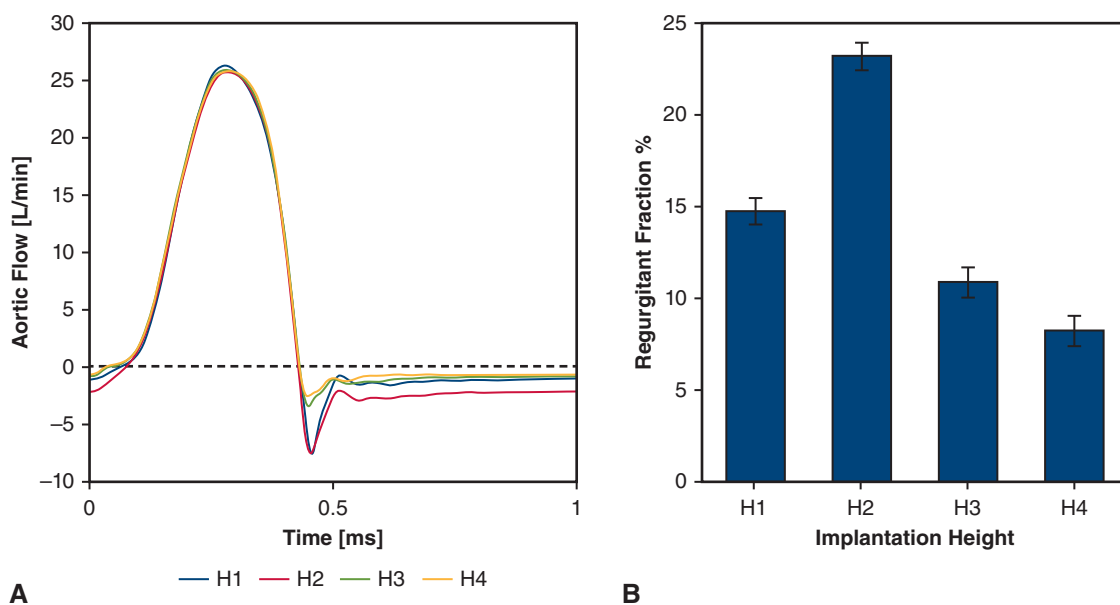


FIGURE 2. Hemodynamics performance of the valve-in-valve at different implantation heights. A, Aortic flow curves. B, Regurgitant fraction. The SDs of the regurgitant fractions are indicated in B.

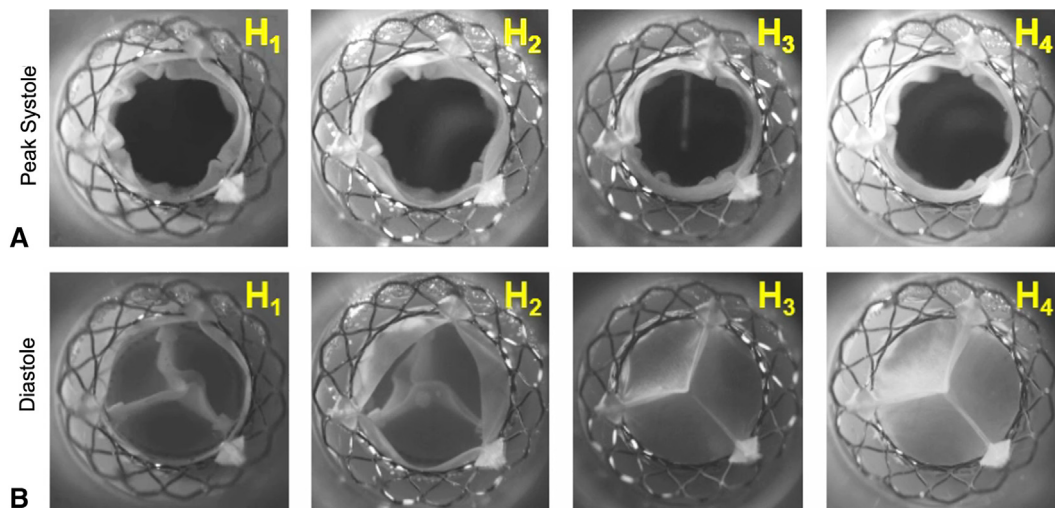


FIGURE 3. En face imaging of the leaflet motion. A, Peak systole. B, Diastole.

and regurgitant flow are similar between H_3 and H_4 cases but are significantly higher for the H_1 and H_2 cases. As shown in Figure 2, B, the RF is the highest for H_2 , reaching $22.8\% \pm 0.8\%$, significantly higher than other cases, and higher than the recommended maximum value of 20% by ISO5840-3:2021. RF for H_1 is $14.5\% \pm 0.7\%$, which is lower than 20% but higher than H_3 and H_4 cases. H_4 has the lowest RF of $8.1\% \pm 0.8\%$.

To observe the kinematics of the leaflets, the en face video was recorded by a high-speed camera at 1000 frames per second. The leaflet motion during acceleration, peak systole, and diastole are shown in Figure 3. For the highest deployment, the Sapien stent pinned the Evolut leaflets to the frame and prevent them from moving, creating a region called the neo-skirt. For H_2 , parts of the leaflets are free to move, causing leaflets to overhang the Sapien valve. This phenomenon is more prominent at diastole. When the deployment height reduces to H_3 , both sets of leaflets are free to move. The observation is similar for the lowest implantation height; that is, H_4 . The calculated EOAs (for Sapien) were comparable between all cases ($1.72 \pm 0.17 \text{ cm}^2$, $1.57 \pm 0.23 \text{ cm}^2$, $1.55 \pm 0.25 \text{ cm}^2$, and $1.69 \pm 0.23 \text{ cm}^2$ for H_1 , H_2 , H_3 , and H_4 , respectively) (Figure 4 and Table 1). The GOAs for H_1 and H_2 are comparable but are much larger for H_3 and H_4 . Because the view of the Sapien leaflets is obscured for H_3 and H_4 during diastole, PI cannot be calculated for them. The PI values for H_1 and H_2 were 12.42% and 18.31%, respectively. The mean PGs for the 4 conditions are $11.8 \pm 0.3 \text{ mm Hg}$, $11.6 \pm 0.5 \text{ mm Hg}$, $12.5 \pm 0.5 \text{ mm Hg}$, and $12.3 \pm 0.5 \text{ mm Hg}$ for H_1 , H_2 , H_3 , and H_4 , respectively, all comparable to each other. The peak and mean PGs are slightly higher for H_3 and H_4 cases there are 2 sets of open leaflets during systole.

Flow Field Downstream of ViV

RSS and velocity vector fields overlaid with z-vorticity contours at peak flow and acceleration phase are shown in Figure 5. During acceleration, the aortic jet starts to develop, and a vortex ring surrounds the aortic jet.¹³ The pinned and overhang leaflets in H_1 and H_2 disrupt the formation of the vortex ring, as shown by the diffused vorticity. For the free-moving leaflets in H_3 and H_4 , the vortex rings have a more regular appearance. It was related to having the closed Evolut leaflets opening and will be beneficial for mixing fluid flow. At peak systole, the aortic jet strengths are similar for all cases and the vorticity distributions are comparable as well. However, for the RSS field, it seems to be the highest for H_1 and the lowest for H_3 . High RSS has been associated with hemolysis.¹⁸⁻²⁰

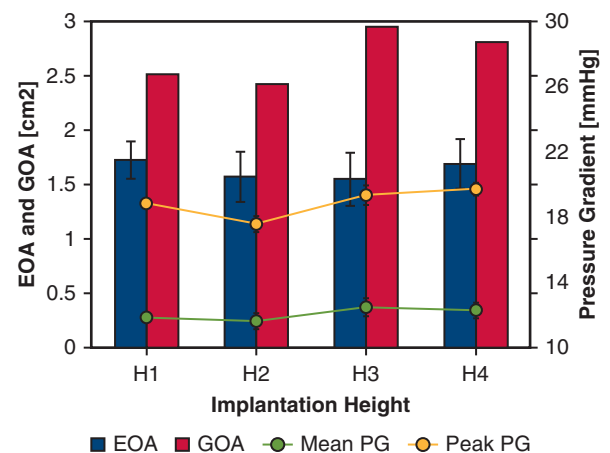


FIGURE 4. Effective orifice area (EOA), geometric orifice area (GOA), and pressure gradients (PGs) for all implantation heights.

TABLE 1. Hemodynamics performances for all configurations

Deployment	Mean TVPG (mm Hg)	Peak TVPG (mm Hg)	Regurgitation fraction (%)	EOA (cm ²)	GOA (cm ²)	Pinwheeling Index (%)
H ₁	11.8 ± 0.3	18.8 ± 0.2	14.5 ± 0.70	1.72 ± 0.17	2.51	12.42
H ₂	11.6 ± 0.5	17.6 ± 0.5	22.8 ± 0.75	1.57 ± 0.23	2.42	18.31
H ₃	12.5 ± 0.5	19.4 ± 0.6	10.7 ± 0.82	1.55 ± 0.25	2.95	N/A
H ₄	12.3 ± 0.5	19.7 ± 0.3	8.1 ± 0.84	1.69 ± 0.23	2.81	N/A

Values are presented as mean ± SD. TVPG, Transvalvular pressure gradient; EOA, effective orifice area; GOA, geometric orifice area; N/A, not available.

DISCUSSION

Leaflet Kinematics and Hemodynamic Performances

The most prominent implication of the implantation height is the motion of the Evolut leaflets. With the highest implantations of Sapien 3 in Evolut (H₁) the stent frame of the Sapien 3 pins the Evolut leaflets to the stent and generates a neo-skirt. With the lower implantations (H₃ and H₄), the leaflets of the Evolut can open and close freely. For the 2 middle implantation heights (H₂ and H₃), the leaflets partially pinned to the skirt can create overhanging leaflets, which remain half-open during diastole.

The first observation of the change in hemodynamic performance is the PG. Due to the requirement to open 2

leaflets, the peak and mean PG for H₃ and H₄ cases are higher than those for H₁ and H₂. In fact, H₂ shows the lowest PG. The en face video shows a delayed opening for the H₃ and H₄ cases (Figure 4).

The second effect is the reduced RF and closing volume when the leaflets of the 2 valves can function properly (H₃ and H₄). There is a significant reduction for H₃ and H₄, whereas RF is the highest for H₂, which might be related to the disruption of the valve closed with the overhang leaflet. The en face video shows a delayed closure for H₂ (Figure 3).

The third is the change in GOA, which shows higher GOA for H₃ and H₄ cases. GOA is the smallest for H₂ cases,

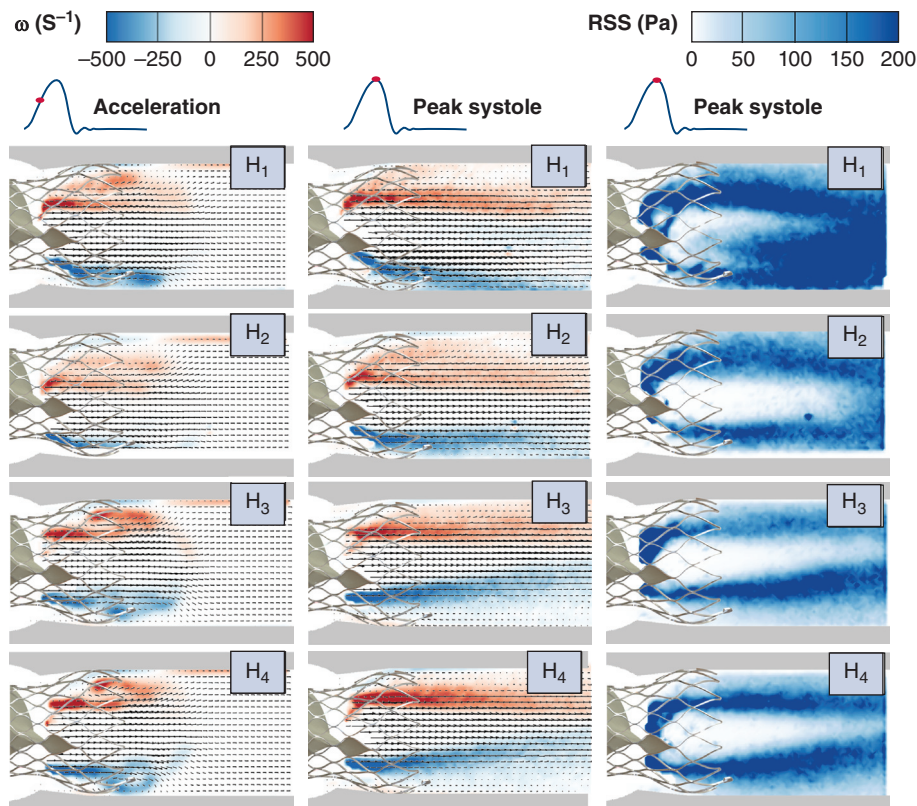


FIGURE 5. Left and middle panels, Phase-averaged velocity vectors over vorticity contours at different phases during a cardiac cycle. Right panel, Principal Reynolds shear stresses (RSS) at peak systole for the different implantation heights.

possibly due to the influence of the overhanging leaflets. The free-to-move Evolut leaflets in H₃ and H₄ cases do not influence the valve opening. Nonetheless, the EOAs are similar across all the valves, which agrees with the observation by Akodad and colleagues.⁸

However, the observations from this *in vitro* study are all based on the fact that the Evolut leaflets are competent, which is usually not the case for a real ViV patient. The most prevalent scenario for valve failure is regurgitation of the first valve, whereas valve stenosis is not that common.²¹ Therefore, when the Sapien implant height is low allowing the Evolut leaflets to move freely, this might only be beneficial to patients in terms of reducing regurgitation. On the other hand, leaving partial leaflet overhang disrupts the flow and vortex formation, causing inferior valve performance.

Effects of Implantation Height on the Flow Field

When 2 valves are opening and closing in series, the flow downstream seems to be dominated by the Evolut leaflets, causing little difference between H₃ and H₄ (Figure 5). However, due to the overhang and pinned leaflets for H₂ and H₁, the flow was disrupted, as shown by the diffused vortex ring and the higher level of RSS. Again, the flow measurements have confirmed that overhanging leaflets are not good for the downstream flow. However, the overhanging configuration has the lowest PG (Figure 4), which might be associated with a larger GOA.

Clinical Implications and Future Directions

When using a balloon-expandable valve to treat the failure of a supra-annular valve, careful presurgery planning should be carried out and current *in vitro* experiments provide valuable insights to the planning. First, when the leaflets are pinned to the stents, there is a slight increase in RF and disruption of the flow with higher RSS. But the PG is low. However, the newly created neo-skirt might be a location for flow stasis and, more importantly, causing coronary artery flow disruptions.⁷ When the second valve is implanted at a lower height, the performance is better, indicated by less regurgitation and only a slight increase in PG. However, this will only be possible if the failed valve was not caused by reduced leaflet motion; that is, stenosis. If the first TAVR fails due to stenosis, the lowest implantation height is expected to perform worse, possibly similar to the cases with overhang leaflets (H₂). Overall, the least desirable option is the medium implantation height when the Evolut leaflets hang over the Sapien leaflets. The disrupted flow causes changes to the leaflet closing dynamics and is therefore associated with high regurgitation. Also, the disruption of the flow causes a reduction of the vortex ring and higher turbulence. Therefore, it is not recommended to leave overhung leaflets. The

results from the current observation are comparable to other studies.^{8,22,23}

CONCLUSIONS

The TAV-in-TAV procedure has gained significant attention as a treatment for failed TAV. However, there is a significant knowledge gap in our understanding of the valve dynamics when 2 valves are present, especially when the first is a supra-annular valve. This *in vitro* study examines the performance and flow field of a redo TAVR using a balloon-expandable valve. Four different implantation heights were evaluated, ranging from leaflets pinned to the original valve stent to overhanging and free-moving. Hemodynamic performance was evaluated using a left heart simulator under physiological conditions. The flow field downstream of the valve was closely examined by phase-locked particle image velocimetry. Results have shown for the bench study, there is no perfect option available. For the pinned leaflets, the closing of the second valve was disrupted, causing high regurgitation. Also, the newly formed neo-skirt might increase thrombosis risk and disrupt access to the coronary arteries. For the free-moving configuration, the PGs are high, especially when the first valve is stenotic. As for the overhang leaflets, they disrupt the flow field downstream of the valve, generating high turbulence and possible disruption of the blood cells.

Although the current study involved 1 size of each valve and on a rigid model without coronaries, some general insights can still be gained. This *in vitro* study showed for a specific case, the best implantation height is associated with the failure mode of the first valve and the specific anatomy of the subject. If the first valve failed because of regurgitation, the lower implantation height (H₃ and H₄) might be beneficial because the free-moving Evolut leaflets are associated with the lowest RF. If the valve failed because of a reduction in leaflet motion, a higher implantation height (H₁) might be desired because the Evolut leaflets are pinned to the stent. However, coronary artery access should be carefully evaluated. Both findings are consistent with the practice proposed by Tarantini and colleagues.²² In any circumstance, the partially overhanging leaflets are not recommended due to higher regurgitation and the disruption of the flow.

Limitations

There are a few limitations to the present study. Only 1 size of each valve was studied. Because there are no clear clinical guidelines on the best practice, different valve sizes will influence the results. However, the authors believe the overall picture regarding the leaflet motion should be the same across different valve size combinations. The experiments were carried out in a rigid and idealized aortic chamber without consideration for the expansion of the primary valve. Only 2-dimensional PIV was used although the flow

was highly 3-dimensional. Also, the flow measurements were limited to downstream of the valve, whereas the flow in the neo-skirt is of great importance and will be the focus of our future studies. Moreover, the Evolut leaflets were flexible, whereas they might be stenotic or structurally damaged for a failed valve, which would influence the results for free-moving leaflets cases (H₃ and H₄). Lastly, the risk of coronary obstruction was not studied.

Conflict of Interest Statement

Dr Dasi reports having patent applications filed on novel polymeric valves, vortex generators, and superhydrophobic/omniphobic surfaces. Drs Dasi, Chen, Samaee, and Thourani have patents pending on predictive computational modeling. Dr Thourani has research or consulting interests with Abbott Vascular, Boston Scientific, Cryolife, Edwards Lifesciences, Medtronic, and Shockwave and is a stockholder of DasiSimulations LLC. Dr Dasi is a cofounder and stockholder of DasiSimulations LLC and YoungHeart-Valve Inc. All other authors reported no conflicts of interest.

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Key Words: TAVR, redo TAVR, implantation height, overhanging leaflet, particle image velocimetry